

# J&J seeks OK for first drug against resistant TB

July 2 2012

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In this Monday, July 17, 2006 file photo, a technician at Ortho-Clinical Diagnostics Inc., a Johnson & Johnson company, works in a "sterile filling" room at the plant in Raritan, N.J. Johnson & Johnson said Monday, July 2, 2012, that it is seeking U.S. approval for the first new type of medicine to fight deadly tuberculosis in more than four decades AP Photo/Mike Derer, File)

(AP) — Johnson & Johnson said Monday that it is seeking U.S. approval for the first new type of medicine to fight deadly tuberculosis in more than four decades.

The experimental drug, called bedaquiline, also would be the first medicine specifically for treating multi-drug-resistant tuberculosis. That's an increasingly common form in which at least two of the four primary TB drugs don't work.

Tuberculosis, caused by bacterial infection of the lungs and other body areas, is the world's No. 2 killer of adults among infectious diseases.

J&J's Janssen Research & Development unit created the drug, which was tested in several hundred patients with multidrug-resistant tuberculosis in two mid-stage studies lasting for six months. Some patients were studied for about 1 1/2 years.

The company this fall is to begin late-stage testing that will compare bedaquiline to dummy pills over nine months in about 600 patients; each will also take six other drugs that are the standard treatments for tuberculosis. That study is aimed at seeing whether treatment for resistant tuberculosis can be reduced to nine months from the current 18 to 24 months recommended by the World Health Organization.

Roughly one-third of the world's population is estimated to be infected with the bacteria causing tuberculosis. It remains latent in most people for many years but can be activated by another infection or serious health problem.

TB is rare in the U.S. but kills about 1.4 million people a year worldwide, with about 150,000 of those succumbing to the increasingly common multidrug-resistant forms.

Janssen's head of infectious diseases, Dr. Wim Pays, said the company will also apply for approval of bedaquiline in other countries where TB is very common.

The disease is a serious problem in developing countries because it takes so long to cure and many patients stop taking their pills once they begin to feel better. That helps bacteria still alive in the patient to develop resistance to the medicines already taken, making future treatment much more difficult.

In afternoon trading, J&J shares rose 31 cents to \$67.87. They are approaching their 52-week high of \$68.05 set almost a year ago.

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